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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,060	03/16/2001	Carl T. Wild	1900.0260001/JMC/SJE	4671

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/809,060	WILD ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,30-36,40 and 41* is/are pending in the application.

4a) Of the above claim(s) *35,36 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,30-34 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 7, and 30-36, 40, and 41 are pending in the application.

2. In the prior action, mailed on August 11, 2006, claims 1, 7, and 30-40 were pending, with claims 35-40 withdrawn from consideration; and claims 1, 7, and 30-34 under consideration and rejected.

3. In the Amendment of November 13, 2006, the Applicant amended claims 1, 7, and 30-33; cancelled claims 37-39; and added claim 41.

4. Currently, claims 1, 7, 30-34, and 41 are under consideration.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claims 1, 7, and 30 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement to extent that they read on embodiments wherein the stabilizing peptides may be fragments of the identified stabilizing peptides. In view of the amendments to the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **(Prior Rejection- Restated as Necessitated by Amendment)** Claims 1, and 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Furata et al. (Nat Struct Biol 5: 276-79) in view of Wild et al., (PNAS 91:9770-74). The claims have been amended to reintroduce embodiments wherein the stabilizing peptide is SEQ ID NO: 1, and to require the presence of an adjuvant in the claimed compositions, and to indicate that the composition is present in a single dose preparation or in a multi-dose flask. It is noted that the Applicant admits in their arguments that both the use of adjuvants, and the single-dose and multi-dose preparations were known in the art, and provides evidence of prior knowledge in the art regarding the single- and multi- dose formulations. In view of the amendment to the claims, the rejection is restated as a rejection of claims 1 and 31 over the teachings of Furata et al. (Nat Struct Biol 5: 276-79) in view of the teachings of Wild et al., (PNAS 91:9770-74) and of LaCasse et al. (Science 283: 357-62- of record in the IDS of April 2002).

The Applicant traverses the prior rejection on the basis that neither the teachings of Furata nor of Wild teach or suggest the formulation of the disclosed complexes with an adjuvant or as a preparation for administration to an animal.

The teachings of Furata and Wild have been described in the prior actions. As indicated in the action of March 27, 2006, the teachings of these references render obvious a composition comprising a conjugate of a stabilizing peptide of either of SEQ ID NOs: 1 or 2 (see e.g., Wild, page 9771, Figure 1), a soluble CD4 receptor, and an HIV gp41/gp120 complex. However, as asserted by the Applicant, these references do not teach or suggest the combination of such with an adjuvant, or the formulation of the compositions as preparations for administration to an

animal. These arguments are found persuasive with respect to the teachings of Furata and Wild alone.

However, the arguments and amendments are not found persuasive when the teachings of wild and Furata are considered in view of the teachings of LaCasse. This reference provides teachings indicating that immunogens comprising a fusion active form of the gp41/gp120 complex are useful for the induction of the neutralizing antibody production in animals. The reference teaches that such immunogens comprise a fusion active form of the gp41/gp120 complex stabilized in its extended (fusion active) form. The reference suggests that "purified fusion-active complexes could be developed as inactivated subunit vaccines." However, the reference does not teach the making of such complexes.

However, from the disclosure of this reference, those of ordinary skill in the art would have looked for such purified complexes for use in anti-HIV vaccines. As was previously disclosed, Furata teaches the production of such purified complexes. See esp., Figure 1(a) description, and Methods section ("Surface co-immunoprecipitation" on pages 278-79). It would therefore have been obvious to those of ordinary skill in the art to use such isolated complexes as the subunit immunogens suggested by LaCasse. Moreover, the teachings of Wild indicate that the stabilizing peptides, versions of which would be exposed in the stabilized fusion active complex, had been identified as a target epitope for a neutralizing antibody. In view of these teachings, in addition to those of LaCasse, those of ordinary skill in the art would have had a reasonable expectation of success in the use of the purified complexes of Furata for the induction of an immune response resulting the production of neutralizing antibodies.

It is also noted that LaCasse teaches the combination of the fusion active immunogens disclosed therein with an adjuvant in the immunogenicity studies. See e.g., Note 12, page 361. In view of these teachings, and in view of the knowledge in the art regarding the use of adjuvants, it would have been obvious to those of ordinary skill in the art to use combine the purified complexes suggested by the references with an adjuvant and to formulate them into appropriate single- or multi-dose preparations.

The combined teachings of Furata in view of Wild and of LaCasse therefore render the claimed inventions obvious. The rejection, as restated, is therefore maintained for the reasons above, and the reasons of record.

8. **(Prior Rejection- Restated as Necessitated by Amendment)** Claims 1, 7, and 30-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Furata in view of Wild as applied to claims 1 and 31 above, and further in view of Haddrick et al. (J Virol Methods 61:89-93). The Applicant traverses this rejection on the same basis as was asserted with respect to the rejection of claims 1 and 30 over the teachings of Furata and Wild above. The rejection is therefore restated as a rejection of claims 1, 7, 30-34, and 41 over the teachings of Furata in view of the teachings of Wild and LaCasse, and further in view of the teachings of Haddrick. It is noted that, in addition to the suggestion of the use of subunit formulations such as are taught by Furata, the LaCasse reference also suggests the use of viral vectors in the indicated anti-HIV immunogenic compositions. See e.g., page 361, center column. Thus, it would have been obvious to those of ordinary skill in the art to have used the embodiments suggested by the

additional teachings of Haddrick as a functional equivalent to the purified protein complexes of Furata.

In view of the restatement of the rejection, the rejection is maintained for the reasons described above (e.g., in the discussion of the rejection of claims 1 and 31), and for the reasons of record.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

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